A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEANS ON SOMATIC AND VASOMOTOR SYMPTOMS AMONG MENOPAUSAL WOMEN RESIDING IN SELECTED COMMUNITY AREA AT KANCHEEPURAM DISTRICT,TAMIL NADU.

By

Ms. A. PFOZA

A Dissertation submitted to

THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY,

CHENNAI.

IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN NURSING

SEPTEMBER- 2014

CERTIFICATE

This is to certify that **"A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEANS ON SOMATIC AND VASOMOTOR SYMPTOMS AMONG MENOPAUSAL WOMEN RESIDING IN SELECTED COMMUNITY AREA AT KANCHEEPURAM DISTRICT,TAMIL NADU. "** is a bonafide work done by **Ms. A . PFOZA, M.Sc (N) II Year Student,** Adhiparasakathi College of Nursing, Melmaruvathur, in partial fulfilment of **THE TAMIL NADU Dr.M.G.R MEDICAL UNIVERSITY** towards the award of the degree of **Master of Science in Nursing, Branch-III, OBSTETRIC AND GYNAECOLOGICAL NURSING,** under my guidance and supervision during the academic year 2012- 2014.

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CHAPTER I

INTRODUCTION

“Woman is the glory of creation”

-Jules Michelet.

Women are given the opportunity to enjoy life and to improve their health then the family as a whole will reap the benefits. But women experience various turning points in her life cycle, which may be developmental or transitional. The transitional changes of a girl start when she attains menarche. Similarly another vital event in women is pregnancy and childbirth, where the women become the mother – the revolutionary act. At last women will reach the stage of menopause in which various physiological and psychological changes will take place. But these are usually neglected by most of the women.

Bimal, 2008 Menopause is one of the woman’s most important life stages. It marks the end of menstruation leading to woman’s aging process when she cannot become pregnant. In other words, it is the physiological cessation of the menstrual cycle associated with advancing age. It is a natural process that happens to every woman as she grows older and not a medical problem, disease or illness, even though it may appear so. Some woman may have a hard time because of the changes of hormone levels during menopause. The average age of menopause is 52 but it can happen anytime between the ages of 42 and 56. A woman can say that she has entered menopause when she has not had periods for a full year**.**

The word “menopause” literally means the “end of monthly cycles” (the end of monthly periods or menstruation), from Greek word “pausis” means cessation and the word root “men-” means month.

Sadhana U et.al, 2009 states that **menopause** is the physiological cessation of menstrual cycles associated with advancing age in any women. It occurs as the ovaries stop producing estrogen, causing the reproductive system to gradually shut down. Women may go through a lot of anxiety, tension, worry, emotional suppression and a lot of physical and mental stress before and during menopause, even if they are aware of its eventuality. If a woman is working the embarrassment gets magnified at her work place. She may show loss of productivity during the day, interruption in important meetings due to frequent trips to bathroom, withdrawal from sexual intimacy. Women needs to know what to expect, why it happens and what measures will help the menopausal women achieve high level functioning at this time in her life. They can understand and provide support for the women’s views and feelings and prepare them for menopause by providing adequate knowledge about it.

Nayak, 2009 stated that most women welcome the end of monthly bleeding, bloating and inconvenience, often leading to frustration in life. For some, it is a time of personal growth and renewal, and to others, it is a challenging period of difficult physical and emotional changes as they find that menopause affects sex life, triggers mood swings, causes debilitating hot flushes and takes them down the road to bone and hearing problems. Each woman reacts to menopause differently. It varies from one woman to another;

and varies among women of different countries and cultures. A woman's experience of menopause can be related to many things including genetics, diet, lifestyle, social, and cultural attitude towards older women.

Somekawa, 2001 Menopausal women suffer from deleterious effects of lowered estrogen levels including reduction of bone mass, hot flush, breathing difficulty, headache, muscle pain, joint pain, faint, dizzy, irritability, excitable, nervous, loss of interest in sex, crying spells and hypercholesterolemia. Those effects are pronounced during menopause because of drastic estrogen reduction. Phytoestrogens can potentially alleviate hypo-estrogen related deleterious effects**.**

Menopause is often accompanied by vasomotor symptoms such as hot flushes and night sweats. Psychological symptoms such as irritability, anxiety, difficulty sleeping and depression, and somatic symptoms such as decreased libido, fatigue and body ache.

Kurzer, M.S, 2001. In some women they can be debilitating as a result, in most of the severe cases exogenous estrogens are prescribed. Given recent reports suggest that Hormone Replacement Therapy may be associated with negative side effects. Many women are hopeful that non- hormonal alternative solutions can be found.

Nikorn, 1996 Hot flushes and night sweats are thermoregulatory disturbances characteristic of the menopause. These symptoms are described as 'recurrent, transient periods of flushing, sweating, and a sensation of heat, often accompanied by palpitation, feeling of anxiety, and sometimes followed by

chills'. Hot flushes start as a sudden feeling of heat in the chest and then spread to the neck and face and are associated with diffuse or patchy flushing of the skin accompanied by profuse sweating. The flushes, which usually last for 3 minutes are induced by vasodilatation which continues for at least 5 minutes after symptoms have subsided. Flushes may be induced by tension or nervousness and their frequency, duration and intensity can be reduced in some subjects with placebo interventions, although estrogen therapy is the most effective treatment**.**

Dusitsin(2009) stated that a large number of other somatic symptoms are 'feeling tense, muscle / joint pain, tiredness, headache, palpitations, dizziness, vaginal dryness, itching labia, bowel disturbances, vaginal discharge, shoulder stiffness' are specific to the menopause. Occurrence of these symptoms is not highly correlated with each other. Stressful life events which are common in the mid-life period frequently precipitate a depressed mood. These symptoms seem to peak during the perimenopause**.**

The North American Menopause Society, 2010 Menopausal hot flashes have been associated with increased anxiety. Anxiety measures are typically composed of items measuring somatic and affective symptoms. Hot flash symptoms are similar to the symptoms of somatic anxiety**.**

Susan Lark, M.D, 2006 Many women choose not to use Hormone Replacement Therapy, or to use it only for a short time. If you don't want to or cannot take Hormone Replacement Therapy, there are a lot of supplements

including herbs, vitamins and minerals and homeopathic remedies that many women find helpful. If osteoporosis is a concern, there are ways other than the use of Hormone Replacement Therapy to prevent and treat bone loss. Changes in lifestyle, diet, and exercise are also beneficial**.**

Soya bean is commonly called as wonder bean since it is an excellent source of nutrients such as proteins, fats, carbohydrates, vitamins and minerals. It contains 43 grams of proteins per 100gms which is the highest among the pulses. It also contains 19.5gms of fat, 21gms of carbohydrate and provides 432 kcal per 100gms.

Schonberg Wee.et.al, (2005) it has been estimated that hot flush incidence is far lower in Asian countries than in the west. Although it is possible that these data are influenced by the reluctance of Asian women to discuss these issues. Between 70 - 80 % of women in the universe and Europe report having hot flush. While only 10 – 20 % of women in Japan, Singapore and China report such symptoms. Given the fact that the soya bean typically consumed in the Asian diet contains the phytoestrogen isoflavones, it has been suggested that soy consumption may be responsible for this difference in symptoms. Recent data suggest that average consumption of isoflavones in Japan is between 15 – 30 mg per day. Whereas in U.S. and in Europe it is 1-2 mg per day. It has thus been suggested that soya consumption may be an effective substitute for post-menopausal than Hormone Replacement Therapy. In fact, recent studies performed in the U.S and Australia suggests that between 16 – 34 % post-menopausal woman consume soya foods and supplements.

Soya is being the most common supplement taken by women who reports the reduction of vasomotor symptoms.

Tomoko, M.D, 2001 In Japan, where soya foods are commonly consumed daily, women are only one-third as likely to report menopausal symptoms as in the United States or Canada. In fact, there is no word in the Japanese language for "hot flashes". Current studies showed that soya only helps some women alleviate menopausal symptoms. Indeed, soya is more effective in preventing than alleviating hot flashes. Despite these findings, the North American Menopause Society in 2000 recommended that 40 - 80mg of isoflavones daily may help relieve menopausal symptoms**.**

NEED FOR THE STUDY

“Woman is a miracle of divine contradictions”. Nature takes her through a series of transitions from birth to death, which includes menarche, pregnancy, labour, motherhood and menopause. Each of this stage stands for different phases in her life which includes both physical and psychological changes. Menopause is the time in women life, when the functions of the ovaries cease. Perimenopause means “the time around menopause” and often refer to the menopausal transitional period.

The median age at menopause in Europe ranges from 50.1 to 52.8 years, in North America from 50.5 to 51.4 years, in Latin America from 43.8 to 53 years and in Asia from 42.1 to 49.5 years. The prevalence rate of menopausal symptoms ranging from 74% of women in Europe, 36 – 50% in

North America and 45 - 69% in Latin America and 22 – 63% in Asia, as reported in different epidemiological studies.

Krajewska.K,2013. Menopause is the time in women's life when her period stops. It usually occurs naturally, bridge often after age 45 years. Menopause happens because the women's ovary producing the hormones the estrogen and progesterone. Changes and symptoms can start several years earlier. They include: changes in periods-shorter or longer, lighter or heavier, with more or less time in between; hot flashes and or night sweats; trouble sleeping; vaginal dryness, mood swings, trouble focusing and less hair on head, more on face. Women, as to men, experience an age-related decline of physical and mental capacity. They observe symptoms such as periodic sweating or hot flushes, depression, insomnia, impaired memory, lack of concentration, nervousness and bone, and joint complaints. Menopause has an impact on women quality of life**.**

WHO Research on menopause, 2011 In World the menopausal women aged 45-59 years suffer from menopausal symptoms. In that 53.1% of menopausal women have no complaints, 5.7% of menopausal women experience hot flushes and 5.2% of menopausal women experience night sweats. Other than this 22.2 % of menopausal woman experience dizziness, 15% experience palpitation, 17.3% experience irritability, 18% experience headache, 16.4% experience insomnia, 2.2 % experience depression**.**

Sagar A Borker et. al, (2012) A community based cross-sectional house to house survey was conducted to find the prevalence of menopausal

symptoms and perceptions regarding menopause among menopausal women of Kerala. The study was conducted among 106 postmenopausal women staying more than 6 months with the help of pretested questionnaire administered by a trained social worker. Data was coded, entered, and analyzed using SPSS 15. Chi-square test, proportions, and percentages were used. The mean age of attaining menopause was 48.26 years. Prevalence of symptoms among ladies were emotional problems (crying spells, depression, irritability) 90.7%, headache 72.9%, lethargy 65.4%, dysuria 58.9%, forgetfulness 57%, musculoskeletal problems (joint pain, muscle pain) 53.3%, sexual problems (decreased libido, dyspareunia) 31.8%, genital problems (itching, vaginal dryness) 9.3%, and changes in voice 8.4%. Only 22.4% of women knew the correct cause of menopause. Thus, the study stated that all the ladies were suffering from one or more number of menopausal symptoms. Ladies should be made aware of these symptoms, their causes and treatment respectively.

Yoshiki, 2013 In India 96% of woman suffer from menopausal problems. Among these: 46.6% from Tamilnadu,31.4% from Andhra Pradesh, 21% from Bihar, 20.25% from Karnataka, 13% from Rajasthan, 11.6% from Kerala**.**

Kanta, 2012. A woman is likely to experience health problems - physical and psychological symptoms – caused by hormonal changes. Physical symptoms: 62% experienced hot sensation, 46%had headache, 58% suffered insomnia, 48% obtained weight gain, 70% had joint and muscle pain, 54% developed back pain, 44% lacked interest in daily activities, and 46%

developed dry skin. Psychological symptoms: 68% had mood swings, 54% developed anger, 54% experienced fatigue, 52% worried during the time of menopause, 40% developed nervousness, and 48% felt depression during the time of menopause**.**

Geller SE, Studee L, (2011), reported that approximately two thirds of women who reach menopause develop menopausal symptoms, primarily hot flushes. Hormone therapy long was considered the first-line treatment for vasomotor symptoms. However, given the results of the Women's Health Initiative (WHI), many women are reluctant to use exogenous hormones for symptomatic treatment and are turning to botanicals and dietary supplement (BDS) products for relief. Despite the fact that there is limited scientific evidence describing efficacy and long-term safety of such products, many women find these natural treatments appealing. Perimenopausal and postmenopausal women are among the highest users of these products, but 70% of women do not tell their healthcare providers about their use.

Carroll DG,(2006) reported the effectiveness of various non-hormonal agents in reducing menopausal hot flash symptoms. Data for these therapies are limited, and most of the studies have been conducted in women with a history of breast cancer. Selective serotonin reuptake inhibitors and venlafaxine have been shown to reduce hot flashes by 19 to 60 percent and were well tolerated by study participants. Soy isoflavones reduced hot flushes by 9 to 40 percent in some trials, but most trials showed no difference compared with placebo. Black cohosh and red clover also have had

inconsistent results, with some trials showing benefit and some no difference compared with placebo. Soy isoflavones, black cohosh, and red clover were well tolerated in clinical trials. Other agents that have been used to alleviate hot flashes include belladonna/ergotamine tartrate/phenobarbital combination, dong quai, evening primrose oil, gabapentin, ginseng, mirtazapine, trazodone, vitamin E, and wild yam, but few data regarding their effectiveness have been published. Further randomized controlled trials are needed.

Jacobs A, et.al.,(2009), review assessed the efficacy of isoflavone supplements to reduce vasomotor symptoms in menopausal women by reviewing all published randomized controlled trials. Systematic literature searches were carried out in 70 databases. Randomized and placebo controlled studies were included if they investigated the treatment of isoflavone supplements derived from soya or red clover on vasomotor symptoms in peri or postmenopausal women for at least 12 wks. Data were analyzed concerning outcome and methodological quality of the study. Twenty-three trials met the inclusion criteria, there of 17 investigated soy isoflavones and 6 red clover isoflavones. As the soy isoflavone studies were very heterogeneous concerning interventions and outcome measures, meta-analysis could not be performed and trials were systematically assessed in a structured approach. Included soy isoflavone studies had numerous quality deficiencies and did not consistently show a reduction of flushes after treatment with soy isoflavones. Therefore, there is no conclusive evidence, but only some indication of a benefit of soy isoflavones on hot flush frequency or severity.

Atmaca A, et.al.,(2008), states that, the effects of soy isoflavones on bone metabolism in postmenopausal woman and their place in the prevention and treatment of postmenopausal osteoporosis. Soy isoflavones are natural products that could be used as an alternative to menopausal hormone therapy because they are structurally and functionally related to 17 beta-estradiol. In vitro and animal studies have shown that they act in multiple ways to exert their bone-supporting effects. They act on both osteoblasts and osteoclasts through genomic and non-genomic pathways. Epidemiological studies and clinical trials suggest that soy isoflavones have beneficial effects on bone mineral density, bone turnover markers, and bone mechanical strength in postmenopausal women. However, there are conflicting results related to differences in study design, estrogen status of the body, metabolism of isoflavones among individuals, and other dietary factors. The long-term safety of soy isoflavone supplements remains to be demonstrated.

Swaminathan, (2007)The health benefits of soy protein, especially for those who take soya protein daily benefits related to the reduction of cholesterol levels and menopause symptoms and the reduction of risk for several chronic diseases**.**

Veeramani, et .al. 2006 A systemic review and meta-analysis of randomized controlled trials were conducted among perimenopausal women to investigate the influence of extracted or synthesized soya bean isoflavones on reduction of menopausal hot flash frequency and its severity. Meta-analysis revealed that ingestion of isoflavones for 6weeks to 12 months significantly

reduce the frequency of hot flash ($p<0.00001$)**.** The result showed that soy isoflavone supplements derived by extraction or chemical synthesis were significantly more effective than placebo in reducing the frequency and severity of hot flush.

St. John's wort, 2012 The evidence to date suggests that black cohosh is safe and effective for reducing menopausal symptoms, primarily hot flashes and possibly mood disorders. Phytoestrogen extracts, including soy foods and red clover, appear to have at best only minimal effect on menopausal symptoms but have positive health effects on plasma lipid concentrations and may reduce heart disease.

Every woman, as she grows older she crosses the natural process – menopause. During this life stage, she may get many symptoms due to the changes in the hormonal level, which affects her normal day-to-day activity. But even in this modern world, a vast majority of women are unaware of menopause and its significance and how to go through this phase of life, for which support from the health professionals are essential to help them to pass through this transition without much difficulty with the use of effective remedies that are available. Therefore, researcher showed much interest in treating the menopausal symptoms. Even in literature the soya beans was found to be safe and effective to treat the menopausal symptoms. So Researcher would like to undertake the soya beans supplementation to know its effect on reducing menopausal symptoms.

STATEMENT OF THE PROBLEM

A STUDY TO ASSESS THE EFFECTIVENESS OF SOYA BEANS ON SOMATIC AND VASOMOTOR SYMPTOMS AMONG MENOPAUSAL WOMEN RESIDING IN SELECTED COMMUNITY AREA AT KANCHEEPURAM DISTRICT,TAMIL NADU.

OBJECTIVES

- To assess the somatic and vasomotor symptoms of menopausal woman residing in selected community area.
- To administer soya beans to the menopausal women among experimental group.
- To compare the effectiveness of soya beans supplementation on somatic and vasomotor symptoms among experimental and control group of menopausal woman.
- To find out the association between post test scores of somatic and vasomotor symptoms among experimental and control group of menopausal woman with their demographic variables.

OPERATIONAL DEFINITIONS

EFFECTIVENESS

It refers to the level of reduction of somatic and vasomotor symptoms in menopausal women in experimental group by using Modified Greene Climacteric Menopausal Symptom Assessment Scale.

SOYABEANS

It refers to 50gm of boiled soya beans supplementation given along with their meals to the menopausal women once a day for 30 days.

SOMATIC SYMPTOMS

It includes

- ✓ Dizziness or fainting
- ✓ Tiredness
- ✓ Headache
- ✓ Muscle and joint pains
- ✓ Palpitation
- ✓ Breathing difficulties
- ✓ Vaginal dryness and labia itching
- ✓ Feeling tense

VASOMOTOR SYMPTOMS

It Includes

- ✓ Hot flushes
- ✓ Sweating at night

MENOPAUSAL WOMAN

It refers to woman after the cessation of menstruation.

SELECTED COMMUNITY AREA

The selected community area includes two villages namely Orathy and Kadamalaiputhur in Acharapakkam at Kancheepuram district,Tamil Nadu.

HYPOTHESIS

Research hypothesis

H_1. There is a significant difference between pre and post test scores of somatic and vasomotor symptoms among menopausal women in the experimental group.

H_2. There is a significant difference between the post interventional level of somatic and vasomotor symptoms of menopausal women among experimental and control group.

H_2. There is a significant association between the post test scores of somatic and vasomotor symptoms among menopausal women and demographic variables in both the experimental and control group.

ASSUMPTIONS:

- Menopausal women aged above 45 years may experience somatic and vasomotor symptoms.
- Soya bean supplementation will reduce the level of somatic and vasomotor symptoms among menopausal women.
- Reduction in the level of somatic and vasomotor symptoms may improve the quality of life.

DELIMITATIONS

The study is delimited to only menopausal women aged 45 – 65 years with somatic and vasomotor symptoms in selected village at kancheepuram district.

PROJECTED OUTCOME

Soya bean supplementation among menopausal women could reduce the vasomotor and somatic symptoms and promote the health status of the menopausal women.

CONCEPTUAL FRAMEWORK OF THE STUDY

A good researcher generally integrates the research findings to an orderly coherent system. Such system is termed as a set of concepts, conceptual framework of the study.

Conceptual framework acts as a building block for the research study. The overall purpose of framework is to make scientific findings meaningful and generalized. It provides a certain framework of reference for clinical practice, education and research.

Conceptual framework is interrelated concepts or abstractions that are assembled together in some rational scheme by virtue of their relevance to a common theme. Conceptual model can be used to stimulate question that can be researched, when research questions are answered by scientific methods, theory can be developed. Conceptual framework provides an organizational scheme involving the new findings of the research with a broader field of knowledge. It helps the researcher in knowing what data need to be collected and gives direction to entire research process.

The Health Promotion Model is a competence or approach oriented model that depicts the multidimensional nature of persons interacting with their concepts applied to physical environments. Those concepts applied to maintain health promotion behavior among menopausal woman.

The Health Promotion Model developed by N.J.Pender,C.L.Murdaugh and M.A.,Pearsons (2002) , focused on three dimensions like individual

characteristics and experiences, behavioral specific cognition and affect and the behavioral outcome.

Individual Characteristics and Experiences

It is unique personal factors or characteristics and experiences which depend on target behavior for health promotion. In the present study, prior related behavioral factors includes family history of menopausal problems, faulty eating habits, lack of exercise, and sedentary life style and experiences of feeling dizzy or faint, pressure or tightness in head or body, numbness or tingling sensation in parts of the body, headaches, muscle and joint pains, loss of feeling sensation in hands or feet, breathing difficulty, hot flushes, and night sweat.

Behavior Specific Cognitions and Affect

This set of variables is considered to be at major motivational significance for acquiring and maintaining health promoting behavior.

Perceived Benefits of Action

Anticipated benefits or outcomes affect the women's plan to participate in health promoting behavior and may facilitate continued practice. In this present study, the menopausal woman, in order to overcome somatic and vasomotor symptoms, decided to participate in soya beans supplementation programme.

Perceived Barriers to Action

It affects health promoting behavior by decreasing the individual commitment to a plan of action. In this present study, the perceived barriers to

action are lack of knowledge about soya beans, difficulty eating soya, and lack of exercise.

Perceived Self Efficacy

It refers to the conviction that a person can successfully carry out the behavior necessary to achieve the desired outcome. In this present study, the perceived self efficacy is providing soya beans supplementation can reduce the somatic and vasomotor symptoms.

Activity Related Affect

The subjective feelings that occur before, during and following an activity can influence whether a person will repeat the behavior again or maintain the behavior. In this study, the researcher motivates the menopausal women to involve in soya beans supplementation.

Interpersonal influence

It refers to a person's perception concerning the behaviors, beliefs or attitudes of others. In this study, the researcher encourages the family and peer group to support menopausal women in involving soya bean supplementation.

Situational Influences

The direct and indirect factor that influence on health promotion behavior. Here mass media, participation on nutritional awareness programmes and discussion among their peer groups are direct and indirect factors that influences the soya beans supplementation.

Commitment to a Plan of Action

Commitment to a plan of action involves two process, commitment and identifying specific strategies for carrying out reinforcing behavior. Here knowledge about soya beans, motivation by the researcher, and their somatic and vasomotor symptoms forces them to carrying out the soya beans supplementation.

Immediate Competing Demands

Competing demands are those behaviors over which an individual has a low level of control to follow. In this study, the menopausal woman are instructed to take 50gms of boiled soya beans for one month, once a day with meals in experimental group and no intervention for control group.

Behavioral Outcomes

Health promoting behavior the outcome of the Health Promotion Model is directed towards obtaining positive health outcomes for the woman. The behavior outcome is the reduction of somatic and vasomotor symptoms among menopausal woman in experimental group and no reduction of somatic and vasomotor symptoms among menopausal woman in control group.

CHAPTER II

REVIEW OF LITERATURE

The review of literature is a broad, comprehensive, in depth, systematic and critical review of scholarly publication, unpublished scholarly print materials audiovisual material and personal communication research problem. The task of reviewing research literature involves the identification, selection, critical analysis and written description of existing information on a topic, (Polit and Hungler, 1999).

The reviews of literature in this study are organized under the following headings:

Part–A: Literature related to somatic and vasomotor symptoms among menopausal woman

Part – B: literature related to soya beans on menopausal symptoms

Part – A: literature related to somatic and vasomotor symptoms among menopausal women.

D'Adamo, Sahin.et al.(2014)

Conducted a study on soya consumption for the health benefits in menopausal women. This review has focused on five health benefits- relief of menopausal symptoms and prevention of heart disease, breast cancer, prostate cancer, and osteoporosis, and 5 health risks-increased risk of breast cancer,

male hormonal and fertility problems, hypothyroidism, anti-nutrient content, and harmful processing by- products. Systematic reviews of human trials, prospective human trials, observational human studies, animal models, in vitro studies, and laboratory analyses of soya components were included for review and found that consuming moderate amounts of traditionally prepared and minimally processed soya foods may offer modest health benefits while minimizing potential for adverse health effects.

Lethaby.A & Marjoribanks. J(2013)

Conducted a study on phytoestrogens for menopausal vasomotor symptoms such as hot flushes and night sweats, are very common during the menopausal transition. No evidence indicated a difference in percentage reduction in hot flushes in two trials between Promensil and placebo. Four trials that were not combined in meta-analyses suggested that extracts with high (> 30 mg/d) levels of genistein consistently reduced the frequency of hot flushes. The study concludes that phytoestrogen (soya) supplements effectively reduce the frequency or severity of hot flushes and night sweats in perimenopausal or postmenopausal women.

Reed ,& Lampe et.al. (2013) conducted a cross sectional population based study on Self-reported menopausal symptoms in a racially diverse population and soya food consumption among peri- or post-menopausal women. Of 18,500 potentially eligible women, 9325 returned questionnaires (50.4% response); 3691 were excluded (premenopausal, missing data, taking hormones). Of 5634 remaining women, 82.1% reported hot flashes ever, 73.1%

reported night sweats ever; 48.8% and 38.6% reported recent hot flashes or night sweats, respectively. Compared with White women, Chinese, Japanese, Vietnamese, other Asian (each $p<0.001$) and Filipino ($p<0.01$) women less commonly reported ever having hot flashes; Asian women less commonly reported recent VMS bother ($p<0.001$). Black women more commonly reported hot flashes ever ($p<0.05$) and recent VMS bother ($p<0.05$). Compared with non-Hispanic White women, Hispanic women were less likely to report hot flashes ($p<0.05$) or night sweats ($p<0.001$) ever. Hence concluded that Menopausal symptoms, independent of isoflavone intake, varied considerably by race/ethnicity and were least common among Asian races.

Carmignani LO.et.al.(2010) A double blind randomized controlled trial study was conducted to compare the effects of daily ingestion of dietary soy supplementation, low-dose hormone therapy (HT) and placebo on psychological, somatic and urogenital symptoms in postmenopausal women. The Menopause Rating Scale (MRS) was used to assess menopausal symptoms at baseline and after 16 weeks of treatment. Comparison between groups revealed a statistically significant improvement in somatic symptoms (hot flashes and muscle pain) in the users of HT (-45.6%) and dietary soy supplementation (-49.8%). Urogenital symptoms (vaginal dryness) improved significantly in HT Users (-38.6%) and in users of the dietary soy supplementation (-31.2%). The study concluded that dietary soy supplementation may constitute an effective alternative therapy for somatic and urogenital symptoms of the menopause.

Ted Ivarsson ,et.al (2009), revealed that mechanisms causing post menopausal vasomotor symptoms are unknown. Changes in hypothalamic beta endorphins have been suggested to be involved beta endorphin production may be increased by regular physical exercise. The women were asked about their physical exercise habits and their complaints from vasomotor symptoms. Only those 793 women who had reached a natural menopause were grouped into sedentary, moderately or high active woman, based on a physical activity score. The study concludes that woman who used hormone replacement therapies were more physically active than non-users (p, 0.05) fewer physically active woman had severe vasomotor symptoms compared with sedentary woman.

North American Menopause Society, (2010), revealed that menopausal hot flushes have been associated with increased scores on measures of anxiety. Anxiety measures are typically composed of items measuring somatic and affective symptoms. Because hot flush symptoms are similar to symptoms of somatic anxiety. The outcome measure was a hot flush score that incorporated both frequency and severity based on a 7-day diary. Higher score on somatic anxiety was significantly associated with higher hot flush score (P=0.04), whereas the association with affective anxiety was not significant (p=0.80). Higher total score on the zung anxiety index (ZAI) was also significantly associated with higher hot flush score (P=0.02). These results suggest that the positive association between higher zung anxiety index (ZAI) scores and hot flushes in recently post menopausal woman may be due to overlap between the

somatic manifestation of hot flush and anxiety symptoms rather than to an affective anxiety disturbance

Srijana M. Bajracharya, (2008) A survey was conducted to assess the knowledge, attitudes, and behaviors regarding menopause and hormone replacement therapy (HRT) issues. A convenience sample of 209 women from Northern Maine was surveyed. The results indicated that half of the women were unaware of the effect of smoking on the onset of menopause. Although most women knew about hormone replacement therapy (HRT) they had very little knowledge about its specific benefits and risks. About 50 to 59 % reported that they would gladly take HRT for different health reasons but 37% of them were anxious because of its unknown long-term effects. The majority (90%) did not believe that menopause is an illness. However, they agreed that education about menopause is extremely important for both men and woman.

Sonia Puri, (2008), A cross study was conducted to ascertain the knowledge about menopause and postmenopausal bleeding in woman of urban and slum area of Chandigarh, India. Out of total 528 woman interviewed, 302 (56.1) were residing in urban area and rest were the residents of slums. 78.8%, urban and 60.2% from slums have attained menopause. Majority (70.3%) of urban residents have heard about menopause as compared to 30.9% in slums. The most common menopausal symptom was vaginal irritation or discharge (42.7%). Less than half of females (38.7%) ever took treatment for menopausal symptoms. Our study highlights that there is lack of awareness regarding

menopause and related aspects especially PMB in both urban and slum population.

Nisar Nusrat,et.al., (2009), A cross sectional survey was conducted to determine the knowledge and attitude of woman towards menopause and to investigate the symptoms experienced by postmenopausal woman. The study revealed that, majority of the woman was unaware of menopausal symptoms and its health effects. Most of them considered it as a natural process of aging, though bothered by symptoms but did not go for consultation due to lack of awareness and poverty.

Newton KM et.al., (2012), A randomized, double-blind, placebo-controlled trial was conducted to test the efficacy of three herbals regimens and hormone therapy for relief of vasomotor symptoms compared with placebo. The difference for hormone therapy versus placebo was -4.06vasomotor symptoms per day for the average over all the follow-up time points (95% CI,-5.93 to -2.19 symptoms per day; p, 0.001) .The trial did not simulate the whole person approach used by naturopathic physicians. Differences between treatment groups smaller than 1.5 vasomotor symptoms per day cannot be ruled out.

Kupferer,et.al (2009), conducted a retrospective single cross sectional descriptive study and explored the use and perceived usefulness of complementary and alternative medicine therapies and non-hormonal conventional medicine alternatives to treat vasomotor symptoms occurring after withdrawal from hormone therapy. With the increased adoption of

complementary and alternative medicine, it is important for health care providers to be familiar with the various methods so they are comfortable discussing the benefits and risks with their patients to assist them in making informed decisions.

Part B: Literature related to soybeans on menopausal symptoms

Am J Clin Nutr. et.al(2014) Conducted a study on effectiveness of Soy foods, isoflavones, and the health of postmenopausal women. Considerable evidence suggests that for soy to reduce risk, consumption during childhood and/or adolescence is required. Although concerns have been raised that soy food consumption may be harmful to breast cancer patients, an analysis in 9514 breast cancer survivors who were followed for 7.4 found that higher post diagnosis soy intake was associated with a significant 25% reduction in tumor recurrence and there is a significant reduction in vasomotor and somatic symptoms among menopausal women. The study indicates that adding soy foods to the diet can contribute to the health of Postmenopausal women.

Sapbamrer,et.al(2013) conducted a study on Effects of dietary traditional fermented soybean on reproductive hormones, lipids, and glucose among postmenopausal women in northern Thailand. The fermented soya bean provided approximately 60 mg of isoflavone per day. The remarkable findings were that dietary fermented soybean had favorable effects on progesterone and cholesterol, but had no effects on estradiol, glucose, and triglycerides. Although estradiol and glucose in the experimental group did not change, a

decrease of estradiol and an increase of glucose were found in the reference group and therefore, suggest that fermented soya bean may have beneficial effects on reproductive hormones and cholesterol.

Bolaños-Díaz, & Zavala-Gonzales (2011) a systematic review and meta-analysis study was conducted to make an indirect comparison of the results from meta-analyses that evaluated the severity of hot flushes in postmenopausal women exposed to hormone therapy (HT) or soya extracts. The combination of the overall results obtained from these two meta-analyses (indirect comparison) was adjusted to the common control (placebo). The calculations yielded a point estimate of -0.84 (95% CI, -1.33 to -0.35) for the indirect SMD favorable to hormone therapy(HT). it was then concluded that HT and soya interventions showed a significant difference in efficacy for the reduction of hot flushes in postmenopausal women when each treatment was compared with placebo.

Washburn S,et.al., (2011),A randomized, double-blind crossover trial was conducted in 51 woman consuming iso caloric supplements containing 20 g of complex carbohydrates (comparison diet), 20 g of soy protein containing 34 mg of phytoestrogens given in a single dose, and 20 g of soy protein containing 34mg of phytoestrogens split into two doses. The study reveals that there is a significant decline in total cholesterol (6% lower) and low density lipoprotein cholesterol (7% lower) were observed in both soy diets compared with the carbohydrate placebo diet. A significant decline in diastolic blood pressure (5 mm Hg lower) was noted in the twice-daily soy diet,

compared with the placebo diet. Adherence was excellent in all groups. Soy supplementation in the diet of non hypercholesterolemic, non-hypertensive, peri menopausal woman resulted in significant improvements in lipid and lipoprotein levels, blood pressure, and perceived severity of vasomotor symptoms.

Welty FK, et.al., (2012), conducted a study on the effect of soya nuts on hot flashes and menopausal symptoms. Sixty healthy post-menopausal woman were randomized in a crossover design to a therapeutic lifestyle changes (TLC) diet alone and a TLC diet of similar energy, fat, and protein content in which one-half cup soy nuts divided into three or four portions spaced throughout the day (containing 25 g soy protein and 101 mg aglycone isoflavones) replaced 25 g of non-soy protein. Soya nut intake was associated with significant improvement in scores on the menopausal symptoms quality of life questionnaire: 19% decrease in vasomotor score , 12.9% reduction in psychosocial score , 9.7% decrease in physical score , and a trend toward improvement in the sexual score, with a 17.7% reduction in symptoms.

Chedraui P,et.al.(2011) A study was conducted to evaluate the effect of soy derived isoflavones over hot flushes, menopausal symptoms and mood in climacteric women with increased body mass index (BMI). After 3 months of soy isoflavone supplementation hot flushes significantly decreased in percentage, number and severity. Menopausal rating scale (MRS) scores reflecting general menopausal symptoms also significantly decreased compared to baseline. Regarding mood, after three months total Hamilton Depressive

Rating Scale (HDRS) scores and the rate of women presenting depressed mood significantly decreased respectively.

Petri Nahas E,et.al., (2010), A prospective, double-blind and placebo-controlled study was conducted to evaluated the effects of isoflavones on vasomotor symptoms and blood lipids in postmenopausal woman with contraindication for conventional hormone replacement therapy (HRT). In both groups, a decreased Kupperman Index (KI) rate was observed. However, isoflavone was significantly superior to placebo in reducing hot flushes. The study concluded that soy germ isoflavone exerted favorable effects on vasomotor symptoms and lipid profile, showing to be an interesting alternative therapy for the postmenopausal woman with contraindication for conventional hormonal replacement therapy (HRT).

Katz DL, Evans MA, et.al., (2009), A randomized double blind, placebo-controlled, cross over trial study was conducted on the effects of raloxifene and soy phytoestrogens on endothelial function in healthy, post menopausal woman. Endothelial function was assessed as flow-mediated vasodilatation (FMD) of the brachial artery using high-resolution ultrasound; digital flux was measured with laser Doppler velocimetry. The study concludes that there is a vascular benefit from the use of selective estrogen receptor modulators or soy phytoestrogens**.**

File SE, et.al., (2009), A double – blind, placebo – matched parallel group study was conducted to assessed the effects of 6 weeks of treatment with

soya supplements on mood, menopausal symptoms, and cognition in postmenopausal woman not taking other forms of hormone therapy. The study revealed that there was a significant reduction in somatic menopausal symptoms in the group taking soya supplements, but there were no other significant effects of soya on menopausal symptoms on mood. On the test of nonverbal short-term memory, the soya group showed greater improvement than the placebo group, but there were no effects of soya on long-term memory, category generation, or sustained attention. However, the soya treatment produced significantly better performance on the two tests of frontal lobe function, those of mental flexibility and of planning ability.

Do MH, et.al., (2007), revealed that the relationship between fruits, vegetables, and soya foods intake with breast cancer risk in Korean woman. High tomato intake was associated with reduced breast cancer risk in Pre-menopausal woman. In post menopausal woman, green pepper intake showed an inverse association of breast cancer. High soyabean intake showed an inverse association of breast cancer in post menopausal women . Our study suggests that high intake of some fruits, vegetables, and soya beans may be associated with a reduced breast cancer risk.

Wetly FK.& lee KS(2012) An epidemiological study was conducted to find the association between soya nuts consumption and menopausal symptoms. The study comprises of 60 menopausal women, selected randomly and they were given soy isoflavones during 6 months. The study findings revealed that 45% decrease in vasomotor symptoms such as hot flashes,12%

reduction in psychological symptoms and 9% decrease in other physical symptoms. The study concluded that there was significant reduction in menopausal symptoms after intervention and soya nut was effective in menopausal symptoms alleviation.

Upmalis DH,et.al., (2011), A double-blind, randomized, parallel group, outpatient, multicenter study was conducted to determine the safety and efficacy of an oral soy isoflavone extract for relief of menopausal hot flushes. A total of 177 post menopausal woman who were experiencing five or more hot flushes per day were randomized to receive either soy isoflavone extract or placebo. Relief of vasomotor symptoms was observed in both groups. Thus the study concludes that soy isoflavone extract was effective in reducing frequency and severity of flushes and did not stimulate the endometrium.

Song et.al. (2010), a longitudinal study was conducted to investigate the effect of soya bean and isoflavone intake on mineral bone density and its change among Korean women and revealed that soybean and isoflavones have a favorable effect on bone mass for postmenopausal woman, but few data are available on young Asian woman. The study revealed that soya bean and isoflavone intake has a positive effect on the change of bone mineral density (BMD) on the femoral neck (FN) and ward's triangle (WT) among young Korean woman.

Dong J, et.al., (2008), A study was conducted to investigate the relationship between estrogen receptor gene Px haplotype and the effect of calcium and soy isoflavone supplementation on bone mineral density (BMD) of Chinese post menopausal women. It was a randomly controlling test for 12 months. After one year fellow-up, the BMD at L2-L4, femur neck site and whole body were significantly decreased as compared with those of baseline, change percent of bone mineral density (BMD) as follows, in observation group, and the whole body mass index (BMD) was significantly lower at 12 month than that at baseline in subjects with Px haplotype , but no difference was found in subjects without Px haplotype. Whole body and femur neck BMD were significantly decreased in both Ca group and Ca + soy isoflavone group, but no significant difference of change percent between two groups.

Hall WL,et.al., (2010)A prospective study was conducted to evaluate the efficacy of soy isoflavones on menopausal symptoms as an alternative to HRT. The 12 month consisted of supplementation of 75 mgs soy isoflavone daily and the menopausal KI was used to assess change in menopausal symptoms. The study result revealed that menopause symptoms were significantly lower ($p<.001$) than the pre-treatment period ($p=0.02$). The study concluded that soy isoflavone treatment was safe and effective alternative therapy for menopausal women.

Basaria S, Wisniewski A,et.al., (2009), A randomized double-blind randomized,placebo-controlled study was conducted to evaluated the effect of high-dose isoflavones on self-reported quality of life (QOL), cognition,

lipoproteins and androgen status in post-menopausal woman. Both soy and the placebo were provided in the form of a powder to be mixed with beverages. There was a significant improvement in all 4 QOL subscales (vasomotor, psychosexual, physical, and sexual) among the woman taking isoflavones, while no changes were seen in the placebo group. Hence, the timing of isoflavone supplementation with regards to the onset of menopause appears to be important.

Charles C, et.al., (2009) A double blind placebo controlled trial study was conducted to identify the effectiveness of soya bean on reduction of menopausal women. The sample were 100 healthy menopausal women not taking any hormonal replacement therapy and the samples were randomly assigned to consume 75mgs isoflavones (study group)25mgs casein protein (control group) daily. The result revealed that there was significantly higher number of cases reported improvement of hot flushes, joint pain and vaginal dryness on soya treatment ($p<0.05$) and controlled group no effect was seen. The study concluded that the soya bean had greater influence on the menopausal symptoms especially on vasomotor symptoms.

Kim HW, et.al., (2009), a cross sectional study was conducted to analyze the relationship between isoflavones intake from soy foods and premenstrual symptoms among woman. There were significant differences in some menstrual symptoms, and postmenstrual symptoms by isoflavones intake levels. These results suggest some positive health effects of isoflavones from soy foods on perimenstrual symptoms. More accurate, objective measurement

needs to be applied and more investigation of soy isoflavones effects on many aspects of woman's health need to be done in a future study.

CHAPTER III

RESEARCH METHODOLOGY

Research methodology is a significant part of any study which enables the researcher to project the research undertaken. Research methodology is the systemic way to carry out an academic study. The methodology enables the research to project a blue print of the details, data, approach; analysis and findings of research undertaken, **(Abdulah, 1979).**

The present study was conducted to evaluate the effectiveness of soya beans on somatic and vasomotor symptoms among menopausal woman.

This chapter includes research approach, research design, setting of the study, variables, population, sample, sample size, sampling techniques, criteria for the sample selection, developing and description of tool, data collection procedure, plan for data analysis and interpretation of the data.

Research Approach

An evaluation research approach was essential to test the effectiveness of the intervention.

Research Design

The research design used for the present study was Quasi experimental design where pre and posttest with control group design was selected.

Setting of the study

Setting for the present study included two selected community area at Acharapakkam namely Orathy and Kadamalaiputhur, which is 12kms away from Adhiparasakthi College of nursing, Melmaruvathur, Kancheepuram district.

Total population of Orathy is 3031. In that female population has 1548, out of which 271 women were above the age of 45 years.

Total population of Kadamalaiputhur is 981. In that female population is 403 out of which 180 women were above the age of 45 years.

Population

The populations for the present study was menopausal woman between 45 – 65 years who have attained menopause and were residing in Acharapakam at Kancheepuram district.

Sample

The samples selected for the present study were menopausal woman between 45 – 65 years with somatic and vasomotor symptoms who were residing in Orathy and Kadamalaiputhur community area at Kancheepuram district and who met the inclusion criteria.

Sample Size

The total sample size was 60 menopausal women, out of which 30 were experimental group and 30 were control group.

Sampling Technique

Snow ball sampling technique was used for the present study.

CRITERIA FOR SAMPLE SELECTION

Inclusion criteria

- Menopausal woman ≥45 years and with somatic and vasomotor symptoms.
- Who were normal physiological processes with somatic and vasomotor symptoms.
- Who gave their oral consent to participate in the study.
- Who were present during the period of data collection.
- Who could understand and speak Tamil or English

Exclusion criteria

Menopausal woman:

- Who had undergone Hysterectomy.
- Who were receiving hormone replacement therapy.
- Who were receiving anticancer therapy.

INSTRUMENTS FOR DATA COLLECTION

Tool is an instrument or apparatus that is necessary in the performance of some task. The scholar constructed the Instrument based on the objectives of the study through literature review and expert's guidance. Instrument for data collection are derived under the following headings like demographic variables, questionnaire method for evaluating the effectiveness of soya bean supplementation on reducing somatic and vasomotor symptoms in menopausal women.

Section: A

This section consists of information about demographic variables such as age of the women, marital status, occupation, educational status, religion, dietary pattern, personal habits and previous source of information about soya bean supplementation on reduction of somatic and vasomotor symptoms among menopausal women.

Section: B

It consists of Modified Greene Climacteric Menopausal Symptom Assessment tool. It is a standardised tool used to assess the somatic and vasomotor symptoms among menopausal woman.

CHAPTER – IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with description of the tool, pilot study report, reliability and validity, informed consent, data collection procedure, score interpretation, method of data analysis plan and results.

TOOL FOR DATA COLLECTION

Demographic variables, modified Greene climacteric menopausal symptoms assessment tool had been used to find out the effectiveness of soya beans on somatic and vasomotor symptoms among menopausal women.

DESCRIPTION OF THE TOOL

The format of the tool consists of two sections.

Section A:Demographic variables of samples.

Section B: Modified Greene climacteric menopausal symptoms assessment tool.

SECTION : A

This section consists of information about Demographic variables such as age, marital status, occupation of the women, educational status, religion, dietary pattern, personal habits, and previous source of information.

SECTION: B

Greene climacteric scale is a validate tool for the research study. It is mainly used to assess the somatic and vasomotor symptoms of the menopausal women.

Based on this scale, the level of somatic and vasomotor symptoms can be categorized into mild, moderate, and severe and the score 1-10 for mild,11-20 for moderate and 21-30 for severe somatic and vasomotor symptoms respectively.

REPORT OF PILOT STUDY

The study was conducted to find out the effectiveness of soya beans supplementation on somatic and vasomotor symptoms among menopausal women. The investigator used snowball sampling technique to select samples and by using modified Greene climacteric menopausal symptom assessment tool, the somatic and vasomotor symptoms had been assessed. There had been statistically reduction in somatic and vasomotor symptoms among menopausal women. The co-operation of the village president and the community members were highly appreciable and the availability of various data and sources were extensively feasible for the study.

RELIABILITY

The structured tools had been used by the investigator to find out the reliability, which were evaluated by the experts in the field. In order to

establish the reliability of the tool, test retest method was used on 6 samples. The coefficient of reliability (R) was 0.82. Reliability and practicability of the tool was tested through the pilot study and used for the main study.

VALIDITY

The tool was prepared by the investigator, based on literature review, under the guidance of experts and on the basis of objectives, was assessed, evaluated and approved by the experts in the field. The content validity of the tool was obtained from various Obstetrics and Gynecological Nursing Experts.

DATA COLLECTION PROCEDURE:

Prior to the collection of the data, permission was obtained from the Panchayat president of Acharapakkam , Kancheepuram district, Tamil Nadu.

The main study was conducted for six weeks among the patients, who met the inclusion criteria, by using snowball sampling technique. The investigator first introduced herself to the patients and established a good rapport with them. The demographic variable were collected from the menopausal women with somatic and vasomotor symptoms pretest was done with the help of modified Greene climacteric menopausal symptoms assessment tool, and 50gms boiled soya beans was supplemented to experimental group and post test was done after 30 day for both the experimental and control group.

SCORING PROCEDURE:

The instrument consists of modified Greene climacteric menopausal symptoms assessment tool used for menopausal women with somatic and vasomotor symptoms. Maximum score was three and the minimum score was one and the net total number of score was 30. The percentage is calculated by using the formula as follows.

$$\text{Score interpretation} = \frac{\text{Obtained score}}{\text{Total Score}} \times 100$$

Based on the percentage of scores the level of symptoms was graded in 3 categories. They are **"Mild", "Moderate" and "Severe"**

SCORE INTERPRETATION:

Table 4.1

Level of Symptoms	Actual Score	Percentage (%)
Mild	1 – 10	Less than 33 %
Moderate	11-20	34 to 67 %
Severe	20-30	68 to 100 %

The data had been organized, tabulated and analyzed by using Descriptive statistics. Mean, standard deviation and paired ‘t’ test were carried out to assess the effectiveness of soya beans supplementation. Chi-sqaure test was used to associate post test scores of somatic and vasomotor symptoms among control and experimental group of menopausal woman.

STATISTICAL METHOD

Descriptive statistical analysis and inferential statistical analysis methods had been used to find out the percentage, mean, standard deviation, Paired ‘t’ test and chi square.

Table: 4.2

S.NO	DATA ANALYSIS	METHODS	REMARKS
1.	Descriptive analysis	The total number of score, percentage of score, mean and standard deviation.	To describe demographic variables of menopausal women with somatic and vasomotor symptoms**.**
2.	Inferential analysis	Paired ‘ t ’ test	Analysing the effectiveness of somatic and vasomotor symptoms among experimental and control group of menopausal woman before and after

			soybeanssupplementation.
3		Independent sample test	Comparing the effectiveness of soya beans on somatic and vasomotor symptoms among experimental and control group
4		Chi square	Analyzing to associate post test scores of somatic and vasomotor symptoms among experimental and control group of menopausal woman with their demographic variables.

DATA ANALYSIS AND INTERPRETATION HAVE BEEN DONE UNDER THE FOLLOWING HEADINGS

SECTION –A Description of samples characteristics..

SECTION – B Assess the somatic and vasomotor symptoms among

experimental and control group of menopausal women before and after soybeans supplementation.

SECTION – C Compare the effectiveness of soya beans on somatic and vasomotor symptoms among experimental and control group of menopausal women

SECTION – D: To find out the association between post test scores of somatic and vasomotor symptoms among experimental control group of menopausal women with their demographic variables.

SECTION - A

DESCRIPTION OF SAMPLES CHARACTERISTICS

Table-4.3

Frequency and percentage distribution of both experimental and control groups of menopausal women according to their demographic variables

Demographic variables of menopausal women with somatic and vasomotor symptoms		Group			
		experimental		Control	
		N	%	N	N %
Age	45-50 years	10	33.3%	6	20.0%
	51-55 years	11	36.7	13	43.3
	above 55 years	9	30.0%	11	36.7%
Marital status	Married	20	66.7%	13	43.3%
	Widow/divorced	10	33.3%	17	56.7%
	Single	0	.0%	0	.0%
Occupation	Home wife	8	26.7%	15	50.0%
	General worker	22	73.3%	15	50.0%
	Professional	0	.0%	0	.0%
Educational status	Illiterate	20	66.7%	8	26.7%
	Primary	7	23.3%	9	30.0%
	Secondary	3	10.0%	13	43.3%
	Graduate	0	.0%	0	.0%
Religion	Christian	0	.0%	12	40.0%
	Hindu	23	76.7%	8	26.7%
	Muslim	7	23.3%	10	33.3%
	Others	0	.0%	0	.0%
Dietary pattern	Veg	0	.0%	14	46.7%
	Non Veg	30	100.0%	16	53.3%
Personal habits	Alcohol	0	.0%	0	0%
	Smoking	0	.0%	0	0%
	Tobacco	11	36.7%	19	36.7%
	None	19	63.3%	11	63.3%
Source of	No	8	26.7%	9	30.0%

Table 4.3 Reveals the frequency and percentage distribution of menopausal women according to their demographic variables.

Distribution of experimental and control group samples according to their age group depicts that the highest percentage (36.7% and 43.3%) of women were in the age group of 51-55 years and however 33.3% and 10.0% of women from each group were in the age group of 45-50 years. Only 30.0% and 36.7% of women from each group were in the age group of 56-60 years. It might be associated with the average age of menopause in India is 50- 55 years.

With regard to marital status, both the experimental and control group samples reveals that 66.7% and 43.3% were married women. However 33.3% and 56.7% were widow/divorce and none of the women were single.

Distribution of experimental and control group samples according to their occupation reveals that (50% and 50%) menopausal women from both the groups were housewives and general worker. It might be associated with the place of study**.**

Regarding educational studies in both the experimental and control group samples reveals that 66.7% and 26.75 were illiterate, 23.3% and 30.05 were primary education and 10.0% and 43.3% studied secondary and none of the women was graduate.

Distribution of experimental and control group sample with regard to religion reveal that 0% and 40.0% belongs to Christian, 76.7% and 26.7% were Hindu and 23.35 and 33.3% belongs to Muslim.

Distribution of experimental control group samples according to their dietary pattern reveal that highest percentages (100% and 53.3%) of the women were non-vegetarian in both the groups. However both in control and experimental group the vegetarian were 0% and 23.3% respectively. Distribution of control and experimental group samples according to their type of personal habits reveals that (36.7% and 63.3%) menopausal women was having the habit of tobacco chewing. However both in experimental and control group none of the menopausal women have the habit of smoking and alcohol and most(63.3% and 33.3%) of the women did not have any bad habits.

With regard to previous source of information in both the experimental and control group samples,26.75 and 30.0% received no information, 6.7% and 30.0% got from family, 33.3% from mass media and 33.3% and 26.7% received information from health care personnel respectively.

SECTION-B

Table 4.4: Frequency and percentage distribution of both the experimental and control group pre and post intervention scores of somatic and vasomotor symptoms among menopausal women

N=60

Level of Somatic and vasomotor symptom		Group			
		Experimental		Control	
		Frequency	Percentage%	frequency	percentage %
Pre test score	mild	2	6.67%	5	16.67%
	moderate	8	26.67%	7	23.33%
	severe	20	66.67%	18	60.00%
Post test Score	mild	21	70.00%	5	16.67%
	moderate	9	30.00%	8	26.67%
	severe	0	0.00%	17	56.67%

Table 4.4: shows that the pre-test and post test level of somatic and vasomotor symptoms based on the modified Greene climacteric menopausal symptoms assessment tool. On the pre-test day most of the menopausal women 20(66.67%) had severe symptoms, 8(26.67%) had moderate symptoms and 2(6.67%)had mild symptom in the experimental and 18(60.00%)had severe symptoms, 7(23.33%)had moderate symptoms and 5(16.67%) had mild symptoms in control group. On post test day, there was a marked reduction in the level of somatic and vasomotor symptoms from severe 20(66.67%) and moderate 8(26.67%) to mild 21(70.00%) and 9(30.00%) among experimental group as compared to control group.

SECTION-C

Table 4.5: Comparison between mean and standard deviation of pre and post test scores of somatic and vasomotor symptoms among menopausal women on the effectiveness of soya beans among experimental and control group.

Table 4.5(a): Mean and standard deviation of pre and post test scores of experimental group

N=30

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Experimental group	Pre test	22.3000	30	4.44235	.81106
	Posttest	12.5667	30	2.58221	.47145

Table 4.5(a): shows that the overall mean of somatic and vasomotor symptoms among menopausal women was 22.30, with the standard deviation of 4.44 in pre test and the mean in post test was 12.56 with 2.58 standard deviation.

Table 4.5(b)Mean and standard deviation of pre and post scores of control group.

N=30

Paired samples test					
		Mean	N	Std. Deviation	Std. Error Mean
Control Group	Pre test	21.3667	30	5.20267	.94987
	Post test	21.3000	30	4.94208	.90230

Table 4.5(b) shows that the overall mean of somatic and vasomotor symptoms among menopausal women was 21.36, with the standard deviation of 5.20 in pre test and the mean in post test was 21.30 with 4.94 standard deviation.

SECTION D

Table4.6: comparison between mean and standard deviation of improvement score for menopausal women with somatic and vasomotor symptoms of both the experimental and control group.

Table 4.6(a): mean and standard deviation of Improvement score of experimental group

N=30

Paired Samples Test								
		Paired Differences					T	P value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			
					Lower	Upper		
Exp grp	Pretest – posttest	9.73333	5.14569	.93947	7.81190	11.65477	10.360*	P<0.05

* Significant at P<0.05

Table4.6(a): revealed that the mean and standard deviation of improvement score for effectiveness of soya beans on somatic and vasomotor symptoms among 30 menopausal women was significant with, mean 9.73, standard deviation 5.14, confidence interval upper 11.65,lower 7.81, ‘t’ value 10.36 and p value <0.05.

4.6(b): Mean and standard deviation of Improvement score of control group

N=30

Paired Samples Test									
		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	Std. Deviation	Std. Error Mean	Lower	Upper	T	df	Sig. (2-tailed)
Cntrl grp	pretest – posttest	.06667	1.04826	.19139	-.32476	.45809	.348#	29	.730

not significant

Table 4.6(b:) revealed that the mean and standard deviation on somatic and vasomotor symptoms among 30 menopausal women was not significant where mean 0.66, standard deviation 1.04,confidence interval upper -.32,lower .45, ‘t’ value .34, df value was 29 and p value was <.730.

Table 4.7: Compare the effectiveness of soya beans on somatic and vasomotor symptoms in menopausal woman among experimental and control groups.

N=60

		Levene's test for equality of varience		t-test for equality of means					
		F	sig	t	P value	Mean difference	Std.error difference	95%confidence interval of the difference	
								lower	upper
Post score	Equal variance assumed	13.564	.001	6.6393*	P<0.05	1.10000	.16435	.77101	1.42899

* Significant at P<0.05

Table 4.7: The computed 't' value(6.63) p<0.05 with the mean difference of 1.10000 shows that there was significant difference between the post interventional level of somatic and vasomotor symptoms among experimental and control group. Thus the finding revealed that soya bean supplementation was effective in reducing the somatic and vasomotor symptoms among menopausal women.

SECTION-E

Table 4.8: Analysing the association between post test scores of somatic and vasomotor symptoms in menopausal women among experimental and control group with their demographic variables.

Sl. No	Demographic variables		Postscore						Chi Square	P value
			Mild		moderate		Severe			
			N	%	N	%	N	%		
1	Age	45-50 years	7	23.33%	4	13.33%	0	0.00%	0.736	0.692
		51-55 years	8	26.67%	2	6.67%	0	0.00%		
		above 55 years	6	20.00%	3	10.00%	0	0.00%		
2	Marital status	Married	14	46.67%	6	20.00%	0	0.00%	0	1
		Widow/ divorced	7	23.33%	3	10.00%	0	0.00%		
		Single	0	0.00%	0	0.00%	0	0.00%		
3	Occupation	Home maker	5	16.67%	3	10.00%	0	0.00%	0.292	0.589
		General worker	16	53.33%	6	20.00%	0	0.00%		
		Professional	0	0.00%	0	0.00%	0	0.00%		
4	Educational status	Illiterate	14	46.67%	6	20.00%	0	0.00%	0.023	0.989
		Primary	5	16.67%	2	6.67%	0	0.00%		
		Secondary	2	6.67%	1	3.33%	0	0.00%		
		Graduate	0	0.00%	0	0.00%	0	0.00%		
5	Religion	Christian	0	0.00%	0	0.00%	0	0.00%	0.71	0.39

		Hindu	17	56.67%	6	20.00%	0	0.00%	9	7
		Muslim	4	13.33%	3	10.00%	0	0.00%		
		Others	0	0.00%	0	0.00%	0	0.00%		
6	Dietary	Veg	0	0.00%	0	0.00%	0	0.00%		
		Non Veg	21	70.00%	9	30.00%	0	0.00%		
7	Personal habits	Alcohol	0	0.00%	0	0.00%	0	0.00%	0.062	0.804
		Smoking	0	0.00%	0	0.00%	0	0.00%		
		Tobacco	8	26.67%	3	10.00%	0	0.00%		
		None	13	43.33%	6	20.00%	0	0.00%		
8	Source of information	No	6	20.00%	2	6.67%	0	0.00%	1.429	0.699
		Family	2	6.67%	0	0.00%	0	0.00%		
		mass media	7	23.33%	3	10.00%	0	0.00%		
		health care	6	20.00%	4	13.33%	0	0.00%		
		any other	0	0.00%	0	0.00%	0	0.00%		

Table 4.9: Shows that there was no significant association between the post test scores of both experimental and control group with demographic variables (**P > 0.05)**. Hence the differences observed in the mean scores values were only by chance and not true difference. It seems that soya beans were effective to all menopausal women irrespective of their demographic variables.

CHAPTER – V

DISCUSSION

This chapter deals with the discussion which was based on the findings obtained from the statistical analysis and its relation to the objectives of the study, the conceptual frame work and the related literature.

This study was used to assess the effectiveness of soya beans on somatic and vasomotor symptoms among menopausal woman residing in selected community area at kancheepuram district. The following were the objectives of this study.

OBJECTIVES

- To assess the somatic and vasomotor symptoms of menopausal women residing in selected community area.
- To administer soya beans to the menopausal women in the experimental group.
- To compare the effectiveness of soybeans supplementation on somatic and vasomotor symptoms among experimental and control group of menopausal women.
- To find out the association between post test scores of somatic and vasomotor symptoms among experimental and control group of menopausal women with their demographic variables

1. To assess the somatic and vasomotor symptoms among control and experimental group of menopausal women before implementation of treatment.

The assessment of the somatic and vasomotor symptoms of menopausal women had been carried out in two community area namely Orathy as experimental group and Kadamalaiputhur as control group at Kancheepuram district. The menopausal women who met the inclusion criteria were selected for the study. The menopausal women with somatic and vasomotor symptoms were assessed with demographic variables and modified Greene climacteric menopausal symptoms assessment tools and each woman were observed and rated by rating scale. In assessment of both the experimental and control group, most of the women, 20(66.67%) and 18(60.00%) had severe symptoms. However, 8(26.67%) from experimental and 7(23.37%) from control group had moderate symptoms and 2(6.67%) and 5(16.67%) had mild symptoms.

2. To administer soya beans to the menopausal women among experimental group.

Based on the above objective of the study, soya beans supplementation was prepared by 50gms of soya bean soaked for 12 – 14 hours, boiled and add a little amount of salt and administered orally once a day to 30 menopausal women (experimental group) aged 45 years and above with somatic and vasomotor symptoms for 30 days in community area of Acharapakkam, kancheepuram district.

3. To compare the effectiveness of soya beans supplementation on somatic and vasomotor symptoms among control and experimental group of menopausal women.

Finding of the pre and post interventional level of somatic and vasomotor symptoms shows that there was a marked reduction in level of somatic and vasomotor symptoms from severe 20(66.67%) and moderate 8(26.67%) to mild 21(70.00%) and moderate 9(30.00%) among experimental group when compared with the control group. It was found that oral administration of soya beans was effective in reduction of somatic and vasomotor symptoms among menopausal women.

4. To find out the association between post test scores of somatic and vasomotor symptoms among control and experimental group of menopausal woman with their demographic variables.

Chi-square was calculated to find out the association between control group post test scores of the menopausal women with their demographic variables regarding soya beans on somatic and vasomotor symptoms. It reveals that there was no significant association between the post test scores of both the experimental and control group when compared to age, marital status, occupation, educational status, religion, dietary pattern personal habits and source of information, (**P > 0.05)**. Hence the differences observed in the mean scores values were only by chance and not true difference. It seems that soya

beans were effective to all menopausal women's irrespective of their demographic variables.

HYPOTHESIS TESTING

H_1. There is a significant difference between pre and post test scores of somatic and vasomotor symptoms among menopausal women in the experimental group.

Null hypothesis

Ho_1. There is no significant difference between pre and post test scores of somatic and vasomotor symptoms among menopausal women in the experimental group.

The data presented in the table 4.5(a) shows that the overall mean of somatic and vasomotor symptoms among menopausal women was 22.30, with the standard deviation of 4.44 in pre test and the mean in post test was 12.56 with standard deviation of 2.58. There is a significant difference between pre and post test scores of somatic and vasomotor symptoms among menopausal women in experimental group. The result reveals that the soya milk was effective on reduction of somatic and vasomotor symptoms among experimental group. Therefore null hypothesis (H_{01}) was rejected and hence the research hypothesis (H_1) is accepted.

H_2. There is a significant difference between the post interventional level of somatic and vasomotor symptoms of menopausal women among experimental and control group.

Null hypothesis

Ho_2. There is no significant difference between the post interventional level of somatic and vasomotor symptoms of menopausal women among experimental and control group.

The data presented in table 4.7 shows the computed 't' value(6.63) $p<0.05$ with the mean difference of 1.10000 which indicates that there was significant difference between the post interventional level of somatic and vasomotor symptoms among experimental and control group. Thus the finding revealed that soya bean supplementation was effective in reducing the somatic and vasomotor symptoms among menopausal women. Therefore null hypothesis (H_{O2}) was rejected and research hypothesis (H_2) was accepted.

H_3. There is a significant association between the post test scores of somatic and vasomotor symptoms among menopausal women and demographic variables in both the experimental and control group.

Null hypothesis

Ho_3. There is no significant association between the post test scores of somatic and vasomotor symptoms among menopausal women and demographic variables in both the experimental and control group

The data presented in table 4.9 Shows that there was no significant association between the post test scores of both experimental and control group with demographic variables(**P > 0.05)**. It seems that soya beans were effective to all menopausal women irrespective of their demographic variables. Hence

null hypothesis (H_{O3}) was accepted and research hypothesis (H_3) was rejected in relation to demographic variables with 5% level of significance.

CHAPTER - VI

SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS

SUMMARY

Somatic and Vasomotor symptoms management is widely discussed in many settings including journals and innumerable studies in the medical and nursing literature. The topic is of great concern because of increased complications like estrogen deprivation stage with long- term symptomatic and metabolic complications.

Although we have advanced technology regarding somatic and vasomotor symptoms management like Hormone Replacement Therapy, Biphosphonates, Selective estrogen receptor modulators (SERMs), Fluoride, Calcitonin. There are some menopausal women in the community area who are having inadequate knowledge regarding soya beans supplementation. Keeping this in view, the investigator aimed at assessing the effectiveness of soya beans supplementation on somatic and vasomotor symptoms among menopausal woman residing in selected community area at kancheepuram district, Tamil Nadu. A total of 60 menopausal women with somatic and vasomotor symptoms who met the inclusion criteria, were selected from Orathi village and Kadaimalaputhur village by using snowball sampling technique.

The investigator first introduced herself and developed a good rapport with them. The demographic variables and the menopausal symptoms were

assessed with modified greene climacteric menopausal assessment tool. Then soya beans had been supplemented for 30 days and posttest was done.

CONCLUSION

From the findings of the study it can be concluded that the highest percentage of woman were in the age group of 51 - 55 years. Most of them were house wives and, consuming non-vegetarian diet and having the habits of tobacco chewing chewing.

- Soya bean was highly effective on somatic and vasomotor symptoms in experimental group.
- There was a significant effectiveness on experimental group than control group menopausal women in somatic and vasomotor symptoms.
- No significant association was observed between experimental and control groups post test scores of menopausal women with their demographic variables.

IMPLICATIONS

This study would provide good insight among the nurses to detect certain problems like dizziness and fainting, headache, muscle and joint pain, hot flushes, night sweats, breathing difficulties, loss of feeling in the hands and other parts of the body, which would guide them to detect measures to reduce the menopausal symptoms and improve the quality of life among menopausal

women. It also meets the challenges among nurses for growing autonomy in decision making to render care to menopausal women.

The study implies that the nurse helps the menopausal women to improve the quality of life. Recovery from menopausal symptoms is more than just curing but improves the quality of life of women.

IMPLICATION FOR NURSING SERVICE

The nursing personnel working in hospital can reinforce the health benefits of soya beans. This method can be used in various settings. The soya bean supplementation can be used to reduce the menopausal symptoms. Nurses should have adequate knowledge regarding the importance of soya bean in menopausal women, so that they could teach the women about its importance to reduce the menopausal symptoms and improve the quality of life.

IMPLICATION FOR NURSING EDUCATION

- Nurse as an educator plays a major role in educating the students regarding pre and post menopausal symptoms. So the nurse educator should educate the nursing professionals about the effectiveness of soya beans on somatic and vasomotor symptoms of menopausal women.
- The researcher educates the menopausal women to add the soybeans in the regular diet to reduce the menopausal symptoms.
- Nurse educator should provide opportunities to the students to gain knowledge regarding the importance of soya beans.

IMPLICATONS FOR NURSING ADMINISTRATION

- With advance technology and ever growing challenges of women's health, the college and hospital administration should have a responsibility to provide nurses, nurse educator and student nurse with continuing education on recent advancement in improving knowledge and skills on women's health.
- The study finding will help the administrator to arrange continuing education programme for nurses about menopausal symptoms. It helps to improve the quality of life.
- Nurse administrator can develop evidence based practice care which will build a strong foundation for providing care to all the women.

IMPLICATIONS FOR NURSING RESEARCH

- There is a need for intensive and extensive research in this area. It opens a big avenue for research on innovative methods of creating awareness, development of teaching materials and setting up of multimedia centers for teaching and creating awareness among women, nurses, public and other health care professionals.
- The study findings will reveal the current knowledge status about menopausal symptoms and the extent to which the knowledge should be improved.
- Further research in this area will help nurses to find out complementary therapies to reduce somatic and vasomotor symptoms.
- This will motivate other investigator to conduct studies in future regarding the same topic.
- This study may be issued for further references. Further large scale study can be done as replication to standardize the soya beans supplementation on somatic and vasomotor symptoms

RECOMMENDATIONS

Based on the findings of the study the following recommendations have been made for the study.

- An experimental study would be undertaken without control group.
- A large scale study can be carried out to generalize the findings.
- A similar study can be conducted for 6 months or 1 year period of time.
- Similar study can be conducted with large sample.
- Quasi experimental studies can be conducted by introducing structured teaching programme
- A study can be conducted to assess the knowledge of menopausal women on complimentary therapies during menopause.
- A comparative study can be conducted to assess the effectiveness of different non – pharmacological management for menopausal symptoms.
- A study can be conducted to assess the effectiveness of complementary and alternative medicine on menopausal symptoms.

SUMMARY

These chapters as dealt with the summary of the study, major findings, conclusions, implications of the study in nursing field and recommendations for future.

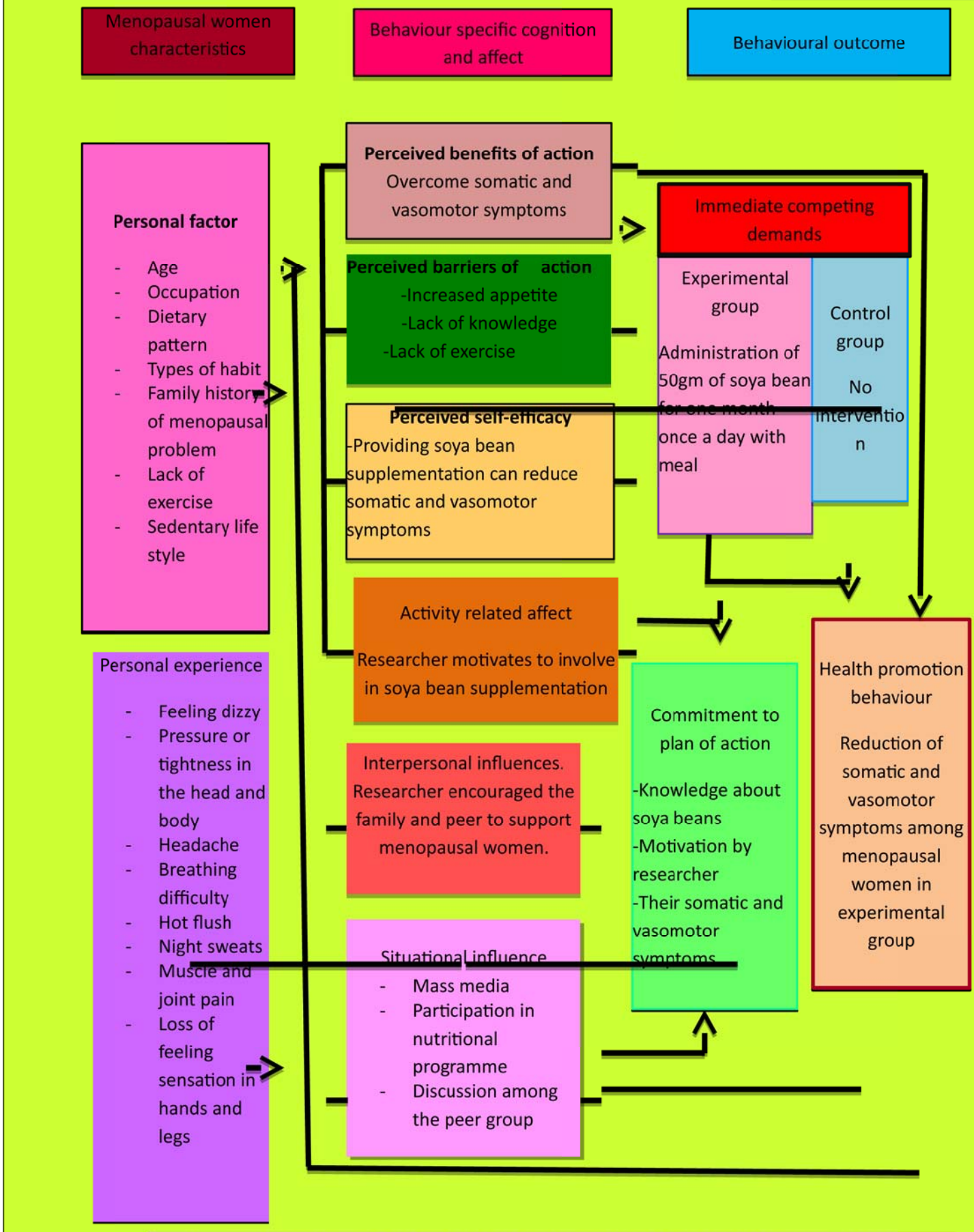

Fig: 4.1 MODIFIED PENDER NJ AND MURDAUGH PEARSONS M.A. HEALTH PROMOTION MODEL (2014)